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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,130	08/27/2002	David Peter Rathjen	18377-0012	2518

46272 7590 06/28/2005

Sutherland, Asbill & Brennan/Atta: Bill Warren  
999 Peachtree Street, NE  
Atlanta, GA 30309-3996

EXAMINER
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NOBLE, MARCIA STEPHENS

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/089,130

Applicant(s)

RATHJEN ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-63 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 4, 20-23, 49, and 51 are drawn to a method of modulating mitosis and differentiation of pluripotent cell cycle by regulating cyclins, classified in class 435, subclass 366.
- II. Claims 5, 32, and 49 are drawn to a method of modulating mitosis and differentiation of pluripotent cell cycle by regulating cyclin-dependent protein kinases (Cdk), classified in class 435, subclass 366.
- III. Claims 6, 7, and 49 are drawn to a method of modulating cell cycle using Cdk inhibitors, classified in class 435, subclass 366.
- IV. Claims 8, 9, 24, and 25 are drawn to a method of modulating cell cycle using tumor suppressor proteins, classified in class 435, subclass 366.
- V. Claims 10, 11, 26, 27, 33, and 34 are drawn to a method of modulating cell cycle using upstream regulators, classified in class 435, subclass 366.
- VI. Claims 13-15, 17, 18, and 53 are drawn to a method of identifying cells by analyzing specific expression of cell cycle regulatory molecules, classified in class 435, subclass 004.
- VII. Claims 15, 16, 18, and 53 are drawn to method of identifying cells by analyzing specific expression of cell cycle structure, classified in class 435, subclass 366.

- VIII. Claims 15, 18, and 55 are drawn to method of identifying cells by analyzing phosphorylation status of tumor suppressor proteins, classified in class 435, subclass 004.
- IX. Claims 36 are drawn to a method of selecting pluripotent cells by cell cycle regulatory molecule expression profiles, classified in class 435, subclass 366.
- X. Claims 37-40 are drawn to a method of selecting pluripotent cells by regulating Cdk inhibitor expression, classified in class 435, subclass 366.
- XI. Claims 42, 43, and 45-47 are drawn to a method of modulating the differentiation status or pluripotency of cells, classified in class 435, subclass 366.
- XII. Claims 54-56 are drawn to pluripotent cells produced by the claimed methods, classified in class 435, subclass 366.
- XIII. Claims 57 and 58 are drawn to multipotent cells produced by the claimed methods, classified in class 435, subclass 366.
- XIV. Claims 59-61 are drawn to embryos and animals produced by stem cell manipulation and selection, classified in class 435, subclass 325.
- XV. Claim 62 is drawn to a method of using pluripotent cells for *ex vivo* therapies, classified in class 435, subclass 325.
- XVI. Claim 63 is drawn to method of using pluripotent cells for drug delivery, classified in class 435, subclass 325.

*Linking Claims*

Claims 1-3, 19, 28-30, 48, and 50 link inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3, 19, 28-30, 48, and 50.

Claims 12 and 52 link inventions VI-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 12 and 52.

Claims 35, 41, and 44 link inventions XI and XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 35, 41, and 44.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In*

*re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I-V are patentably distinct each from the other because they are drawn to methods that have distinct steps and use reactants that have distinct structure, function, and utility. For example, the method of group I requires cyclin regulation, while the method of group II requires Cdk regulation. In contrast to these two groups, group IV requires a tumor suppressor protein while group III requires a Cdk inhibitor. Searches for the reactants used in groups I-V will not be coextensive, for example, searching for cyclin will not be coextensive with that of tumor suppressor proteins, Cdk, or Cdk inhibitors.

Inventions of the groups VI-IX are patentably distinct each from the other because they are drawn to methods that have distinct steps and use reactants that have distinct structure, function, and utility. For example, the method of groups VI and IX require analysis of cell cycle regulatory molecules from pluripotent cells, while the method of group VII requires analysis of cell cycle structure. In contrast to these two groups, group VIII requires the analysis of phosphorylation status of tumor suppressor proteins. Searches for the reactants and structural elements used in groups VI-IX will not be coextensive, for example, searching for cyclin, Cdk, or Cdk inhibitors will not be coextensive with cell cycle structural elements.

The inventions in groups XII and XIII are distinct because pluripotent cells have additional capabilities and greater potential uses compared to multipotent cells because

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pluripotent cells are less differentiated than pluripotent cells. Therefore, searching for pluripotent cells will not yield art relevant to multipotent cells. Similarly the invention in group XIV is related to those of groups XII and XIII as being derived from the cells of groups XII and XIII but they are distinct because cells of groups XII and XIII can be used for patentably distinct utilities , such as a method of treatment as described in group XV or drug delivery as described in group XVI.

Inventions in groups I-X and X-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells and embryo can be used to develop new drug therapies and animals can be used disease treatment models, drug production, or improved food production.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

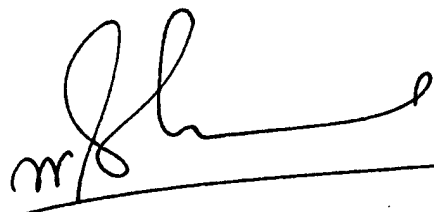
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shukla Ram can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcia S. Noble

  
**RAM R. SHUKLA, PH.D.**  
**SUPERVISORY PATENT EXAMINER**